(5) Whether payment (financial or otherwise) may be provided to a child or his or her parent, guardian, or legally authorized representative for the participation of the child in research, and if so, the amount and type of payment that may be made.

(6) Compliance with the regulations referred to in subsection (a)(1)(A), the monitoring of such compliance (including the role of institutional review boards), and the enforcement actions taken for violations of such regulations.

(7) The unique roles and responsibilities of institutional review boards in reviewing research involving children, including composition of membership on institutional review boards.

(c) REQUIREMENTS OF EXPERTISE.—The Institute of Medicine shall conduct the review under subsection (a)(1) and make recommendations under subsection (a)(2) in conjunction with experts in pediatric medicine, pediatric research, and the ethical conduct of research involving children.

SEC. 11. TECHNICAL AND CONFORMING AMENDMENTS.

Section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) (as amended by sections 2(1), 4(b)(2), 8, and 9) is amended—

(1)(A) by striking ''(j)(4)(D)(ii)'' each place it appears and inserting ''(j)(5)(D)(ii)'';

(B) by striking ''(j)(4)(D)'' each place it appears and inserting ''(j)(5)(D)''; and

(C) by striking ''505(j)(4)(D)'' each place it appears and inserting ''505(j)(5)(D)'';

(2) by redesignating subsections (a), (g), (h), (i), (j), (k), (l), (m), and (n) as subsections (b), (a), (g), (h), (m), (l), (i), (j), and (k), respectively;

(3) by moving the subsections so as to appear in alphabetical order;

(4) in paragraphs (1), (2), and (3) of subsection (d), subsection (e), and subsection (m) (as redesignated by paragraph (1)), by striking ''subsection (a) or (c)'' and inserting ''subsection (b) or (c)''; and

(5) in subsection (g) (as redesignated by paragraph (1)), by striking ''subsection (a) or (b)'' and inserting ''subsection (b) or (c)''.

Mr. HATCH. Mr. President, I rise to commend my colleagues Senators DEWINE and DODD for their efforts to reauthorize an important piece of legislation—the pediatric exclusivity rules. The DeWine-Dodd pediatric exclusivity law was passed as part of the Food and Drug Administration Modernization Act of 2001. This bill has helped spur a great deal of research into pediatric indications for many pharmaceutical products. It is a good law.

I also want to recognize the efforts of Chairman KENNEDY and Ranking Member GREGG and Senator FRIST for their work in moving this through the HELP Committee.

I am offering a technical amendment that I believe will be acceptable to all, that clarifies how the pediatric exclusivity provisions work in conjunction with certain provisions of the Drug Price Competition and Patent Term Restoration Act. Representative WAXMAN and I were instrumental in developing this important 1984 law.

I have worked with my colleagues, the administration, and interested parties to make certain that the 1997 pediatric exclusivity law does not act to curtail the incentives of those generic drug manufacturers awarded 180 days of exclusivity under the 1984 law because they have successfully challenged a patent or have shown that a pioneer drug product is not infringed.

The amendment I offer today helps make clear that a generic firm that qualifies for the 180-day patent noninfringement/patent invalidity incentives gains just that—180 days, no more, no less.

I also thank Senator DODD for agreeing to continue to work to iron out some issues as this bill is conferenced with the House. For example, we want to work together to make certain the overlap language applies to generic drug applications already in the pipeline at FDA. I also understand that some may have concerns that certain aspects of this language may raise questions with respect to the takings clause. It is my hope that the conferees will work to perfect the language.

I commend Helen Rhee, who has worked on this bill for both her old boss, Senator DEWINE and her new boss Senator FRIST and Deborah Barrett of Senator DODD's office for their work on this bill.

I also commend the expert staff of the Food and Drug Administration, including Melinda Plaisier, Jarilyn DuPont, Liz Dickinson, and Kim Dettelbach for their hard work on this legislation.

I urge my colleagues to work together to reauthorize the DeWine-Dodd pediatric bill.

Mr. FRIST. Mr. President, I rise today to support S. 838, the Best Pharmaceuticals for Children Act. In the January 2001 report to Congress, the FDA stated that the law that we are reauthorizing today, ''has done more to generate clinical studies and useful prescribing information for the pediatric population than other regulatory or legislative process to date.''

In just the 3 years since the law was implemented, it has made a positive difference in the lives of thousands of children. I am pleased to be a cosponsor and strong supporter of this highly successful program. In the short time that this program has been in existence, FDA has issued about 200 written requests for pediatric studies. Companies have undertaken over 400 pediatric studies, of which 58 studies have been completed, in a wide range of critical therapeutic areas, including gastro esophageal reflux disease, diabetes mellitus, pain, asthma, and hypertension. Thirty-seven drugs have been granted pediatric exclusivity, and important label changes have either been made, or are underway, as a result of pediatric studies.

For instance, new pediatric dosing information for a new oral formulation of midazolam, a medication used to sedate children in surgery, now offers an alternative to the injectable form of the drug that needs to be directly injected into a child's vein. The studies submitted under this pediatric exclusivity law not only resulted in this new oral syrup formulation and correct dosing information, but also identified a subpopulation of pediatric patients with heart disease and pulmonary hypertension who are at higher risk for adverse events unless they are given lower doses than other children. A pediatric nephrologist from Memphis, TN, prescribed Randitidine, using new dosing and labeling information that resulted from this law, to neonates who were experiencing health problems due to acid reflux.

Despite the successes of this law, we did not settle for a straight reauthorization. We instead sought to improve this already highly successful law. This law provides a funding mechanism to ensure that off-patent drugs and certain declined written requests for the study of on-patent drugs, for which the Secretary believes there is a continuing need for pediatric testing, are studied. It establishes timeframes for responding to written requests, timeframes and processes for negotiating label changes, and authorizes the Federal Government to deem a drug misbranded if the company ultimately disagrees with FDA's proposed new drug label. The government could then begin an enforcement action under existing authority to seek a court order regarding relabeling of the drug.

We also lift the current restrictions on user fees established under the Prescription Drug User Fee Act to include this pediatric testing program. By including pediatric testing in the user fee program, the FDA will be given additional resources needed to give priority review to pediatric testing applications.

We provide for the public dissemination of summaries of the pediatric studies that are submitted so that certain unprotected information will be disseminated to pediatricians even before labeling information has been finalized.

I would like to thank Senator HATCH and his staff, Bruce Artim and Trish Knight, for their work in drafting language to clarify that this pediatric incentive program does not, and is not intended to, preclude other incentives, for example, one that provides for a 180-day exclusivity period for the first generic drug company that challenges a patent. Another important clarification we made in this bill is that the pediatric exclusivity program is not intended to prevent generics from entering the market solely based on the fact that some or all of the pediatric use information may be protected under the pediatric exclusivity law. Allowing generic drug companies to market a drug to adults, while requiring that any precautions, warnings, or contraindication for pediatric use that the Secretary determines to be necessary ensures that the safety of children is protected and that the intent of two different laws are both met.

To further ensure that the safety of children in clinical trials is protected, this bill requires that the Institute of Medicine conduct a review of federal regulations, reports, and research involving children and provide recommendations on best practices relating to research involving children. This